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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,652	01/15/2002	Manuel L. Penichet	306J-001700US	8739
22798 7590 10/16/2007 QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C. P O BOX 458 ALAMEDA, CA 94501			EXAMINER SANG, HONG	
			ART UNIT 1643	PAPER NUMBER
			MAIL DATE 10/16/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/051,652

Applicant(s)

PENICHER ET AL.

Examiner

Hong Sang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/9/07.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 1-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RE: Penichet et al.

1. Applicant's response filed on 8/9/07 is acknowledged. Claims 1-31 are pending. New claim 31 is added. Claims 1-22 are withdrawn from consideration as being drawn to non-elected inventions. Claims 23, 24, and 27-29 are amended.
2. Claims 23-31 are under examination.

Rejections Withdrawn

3. The rejection of claims 23-30 under 35 U.S.C. 102(b) as being anticipated by Penichet et al (J. Immunol. 1999, 163: 4421-4426, see IDS), as evidenced by Zerega et al. (J. Cell Science, 2001, 114: 1473-1482) is withdrawn in view of applicant's amendment to the claims.

Response to Arguments

Claim Rejections - 35 USC § 112, 1st paragraph

4. The rejection of claims 23-26, 28-30 and new claims 31 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

The response states that the claims have been amended to recite an antibody as the targeting moiety.

The amendment to the claims to recite an antibody as the targeting moiety is insufficient to overcome the rejection. Although the targeting moiety is limited to an antibody, the amended claims still encompass a genus of cell surface receptors or

carbohydrates that an antibody can bind. As indicated in the previous office action (see office action mailed on 8/23/05, page 5, and office action mailed on 1/12/06, page 8, lines 4-8), the specification also lacks written description on the broadly recited cell surface receptor or carbohydrates. The specification describes only a transferring receptor. Therefore, only the transferring receptor but not the full breadth of "cell surface protein or carbohydrate" meets the written description. Because of these reasons, the rejection is maintained.

Claim Rejections - 35 USC § 102

5. The rejection of claims 23-30, and new claim 31 under 35 U.S.C. 102(a) as being anticipated by WO 01/07084 (see IDS), as evidenced by Kemp et al. (Pathobiology, 1992, 60: 27-32, IDS) is maintained.

The response states that WO 01/07084 does not teach the composition comprises one or more human cells which are to be inhibited or to undergo apoptosis.

Applicants' arguments have been carefully considered but are deemed not to be persuasive. WO 01/07084 teaches a fusion protein comprising a first segment and a second segment: the first segment comprising a variable region of an antibody that recognizes transferring receptor (claims 6-7) and further comprises at least one domain of a constant region of an antibody; and the second segment comprising a protein domain selected from the group consisting of avidin, an avidin mutein, a chemically modified avidin derivative, streptavidin, etc (Claim 1). WO 01/07084 teaches that the cells to be targeted can be any cells bearing a surface receptor recognized by the

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antibody (see page 8, lines 15-16). WO 01/07084 states that if the antigen is on the surface of a human cell, it can be, but is not limited to, the human transferrin receptor (see page 7, lines 1-2). Therefore, the cells to be targeted include human cells that express transferrin receptor.

6. The rejection of claims 23-26, 28-30, and new claim 31 under 35 U.S.C. 102(b) as being anticipated by Schultz et al., (Cancer Res. 2000, 60: 6663-6669), as evidenced by Stone et al. (Proceeding Am. Assoc. Cancer Res. Annual Meeting, 2002, 43: 881, IDS) is maintained.

The response states that the recited antibody, and antibody fragments as in the amended claims are distinct from scFv constructs of Schultz. Applicants appear to argue that the claimed antibody or fragments thereof does not include scFv.

Applicant's arguments have been carefully considered but are not persuasive. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Claims terms are interpreted not only in light of the specification but also in light of the prior art. *In re Cortright*, 49 USPQ2d 1464, 1467 (Fed. Cir. 1999). Thus, when "antibody" is given its broadest reasonable interpretation, it includes scFv. Schultz et al. teach that the immunoreactivity of the scFv-straptavidin fusion protein and its nanomolar affinity to CD20-positive Ramos cells were comparable with the B9E9 monoclonal antibody (see abstract). The Ramos cells are human Burkitt lymphoma cells (see page 6665, 3rd paragraph).

New Grounds of Rejections

Claim Rejections - 35 USC § 112, 2nd paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 recites the limitation "targeting moiety" in claim 23. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 112, 1st paragraph

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 23-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a **new matter** rejection.

The terms "human cells" and "one or more of said cells" recited in the claims are considered new matter since the specification, drawings and claims as filed disclose only the human erythroleukemia cell line (see Examples 3-5). The scope of the

specification is limited to human erythroleukemia cell line and the use of any human cells or cell lines is a broadening of the scope. Furthermore, there is no clear support for a composition comprising a cytotoxic agent, one or more of human cells and a pharmaceutical carrier. Applicants pointed to the Examples for support (see response page 7, 2nd paragraph), however, only the human erythroleukemia cells are found.

If applicant believes that support for the above-mentioned phrases or terms is present in the specification, claims or drawing as originally filed, applicant must, in responding to this action, point out with particularity, where such support may be found.

Applicant is required to cancel the new matter in the reply to this Office Action.

Conclusion

11. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hong Sang
Art Unit: 1643
Sept. 25, 2007

/Christopher Yaen/
Primary Examiner
Art Unit 1643
October 10, 2007